



45

RULE 63 (37 CFR § 1.63)  
DECLARATION FOR PATENT APPLICATION  
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

I hereby declare that my residence, post office address and citizenship are as stated below next to my name, and I believe I am an original, first and joint inventor, together with Marco Guida of 3899 Nobel Drive, #1301, San Diego, California 92122, Jeff Hall of 7226 Columbine Drive, Carlsbad, California 92009, William P. Petros of 2 Bermouth Court, Durham, North Carolina 27705, James J. Vredenburg of 100 Silver Glade Place, Chapel Hill, North Carolina 27514, Oliver M. Colvin of 208 Arcadia Lane, Chapel Hill, North Carolina 27514, and Jeffrey R. Marks of 4233 New Hope Spring Drive, Hillsborough, North Carolina 27278, of the subject matter which is claimed and for which a patent is sought on the invention entitled "METHODS FOR EVALUATING THE ABILITY TO METABOLIZE PHARMACEUTICALS AND COMPOSITIONS THEREFOR," the specification of which was filed on February 26, 2002, receiving Serial No. 10/085,612, and further identified as Attorney File No. 4389-5-C1.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to patentability in accordance with 37 CFR 1.56(a) and (b) as set forth on the attached sheet indicated Page 4 hereof, which I have read.

I hereby claim priority benefits under 35 U.S.C. 119(e) of any provisional application(s) for patent listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in such prior applications in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information material to patentability in accordance with 37 CFR 1.56(a) and (b) which occurred between the filing date(s) of the prior application(s) and the national or PCT international filing date of this application:

<u>Application Serial No.</u>	<u>Filing Date</u>	<u>Status</u>
60/271,630	February 26, 2001	Abandoned

I hereby claim the benefit under 35 U.S.C. 120/365 of all United States and PCT international applications listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in such prior applications in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information material to patentability in accordance with 37 CFR 1.56(a) and (b) which occurred between the filing date(s) of the prior application(s) and the national or PCT international filing date of this application:

<u>Application Serial No.</u>	<u>Filing Date</u>	<u>Status: patented, pending, abandoned</u>
n/a		

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

(1) Inventor's Signature \_\_\_\_\_ Date \_\_\_\_\_

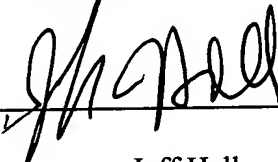
Inventor's Name (typed): Marco Guida

Citizenship: Italy

Residence: 3899 Nobel Drive, #1301  
San Diego, California 92122

Post Office Address\*: Same as Residence

\*Complete Post Office Address in full if different from Residence, otherwise indicate that the Post Office Address is "Same as Residence."

(2) Inventor's Signature  \_\_\_\_\_ Date May 15, 2002

Inventor's Name (typed): Jeff Hall

Citizenship: U.S.A.

Residence: 7226 Columbine Drive  
Carlsbad, California 92009

Post Office Address\*: Same as Residence

\*Complete Post Office Address in full if different from Residence, otherwise indicate that the Post Office Address is "Same as Residence."

(3) Inventor's Signature \_\_\_\_\_ Date \_\_\_\_\_

Inventor's Name (typed): William P. Petros

Citizenship: U.S.A.

Residence: 2 Bermouth Court  
Durham, North Carolina 27705

Post Office Address\*: Same as Residence

\*Complete Post Office Address in full if different from Residence, otherwise indicate that the Post Office Address is "Same as Residence."

(4) Inventor's Signature \_\_\_\_\_ Date \_\_\_\_\_

Inventor's Name (typed): James J. Vredenburg

Citizenship: U.S.A.

Residence: 100 Silver Glade Place  
Chapel Hill, North Carolina 27514

Post Office Address\*: Same as Residence

\*Complete Post Office Address in full if different from Residence, otherwise indicate that the Post Office Address is "Same as Residence."

(5) Inventor's Signature \_\_\_\_\_ Date \_\_\_\_\_

Inventor's Name (typed): Oliver M. Colvin

Citizenship: U.S.A.

Residence: 208 Arcadia Lane  
Chapel Hill, North Carolina 27514

Post Office Address\*: Same as Residence

\*Complete Post Office Address in full if different from Residence, otherwise indicate that the Post Office Address is "Same as Residence."

(6) Inventor's Signature \_\_\_\_\_ Date \_\_\_\_\_

Inventor's Name (typed): Jeffrey R. Marks

Citizenship: U.S.A.

Residence: 4233 New Hope Spring Drive  
Hillsborough, North Carolina 27278

Post Office Address\*: Same as Residence

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37 CFR §1.56(a) and (b)  
DUTY TO DISCLOSE INFORMATION MATERIAL  
TO PATENTABILITY

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

(1) prior art cited in search reports of a foreign patent office in a counterpart application,  
and

(2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or

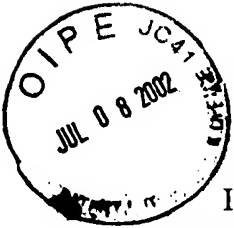
(2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) Opposing an argument of unpatentability relied on by the Office, or

(ii) Asserting an argument of a patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.\*

\*Note, 37 CFR §1.97(h) states: "The filing of an information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in §1.56(b)."



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OFFICE OF PETITIONS

(1) Inventor's Signature \_\_\_\_\_ Date \_\_\_\_\_

Inventor's Name (typed): Marco Guida

Citizenship: Italy

Residence: 3899 Nobel Drive, #1301  
San Diego, California 92122

Post Office Address\*: Same as Residence

\*Complete Post Office Address in full if different from Residence, otherwise indicate that the Post Office Address is "Same as Residence."

(2) Inventor's Signature \_\_\_\_\_ Date \_\_\_\_\_

Inventor's Name (typed): Jeff Hall

Citizenship: U.S.A.

Residence: 7226 Columbine Drive  
Carlsbad, California 92009

Post Office Address\*: Same as Residence

\*Complete Post Office Address in full if different from Residence, otherwise indicate that the Post Office Address is "Same as Residence."

(3) Inventor's Signature Will P. Petros Date 5/28/02

Inventor's Name (typed): William P. Petros

Citizenship: U.S.A.

Residence: 5/28/02 WP ~~2 Bermouth Court~~ 901 Riverview Drive  
~~Durham, North Carolina 27705~~ Morgantown, WV 26505

Post Office Address\*: Same as Residence

\*Complete Post Office Address in full if different from Residence, otherwise indicate that the Post Office Address is "Same as Residence."

(4) Inventor's Signature James J. Vredenburg Date 5/23/02

Inventor's Name (typed): James J. Vredenburg

Citizenship: U.S.A.

Residence: 100 Silver Glade Place  
Chapel Hill, North Carolina 27514

Post Office Address\*: Same as Residence

\*Complete Post Office Address in full if different from Residence, otherwise indicate that the Post Office Address is "Same as Residence."

(5) Inventor's Signature Oliver M. Colvin Date 5/23/02

Inventor's Name (typed): Oliver M. Colvin

Citizenship: U.S.A.

Residence: 208 Arcadia Lane  
Chapel Hill, North Carolina 27514

Post Office Address\*: Same as Residence

\*Complete Post Office Address in full if different from Residence, otherwise indicate that the Post Office Address is "Same as Residence."

(6) Inventor's Signature Jeffrey R. Marks Date 5/27/02

Inventor's Name (typed): Jeffrey R. Marks

Citizenship: U.S.A.

Residence: 4233 New Hope Spring Drive  
Hillsborough, North Carolina 27278

Post Office Address\*: Same as Residence

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and

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(2) It refutes, or is inconsistent with, a position the applicant takes in:

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\*Note, 37 CFR §1.97(h) states: "The filing of an information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in §1.56(b)."



## POWER OF ATTORNEY

On behalf of Duke University, having a principal place of business at Erwin Road, Durham, North Carolina 27708, being the assignee and owner of all right, title and interest in the invention entitled "METHODS FOR EVALUATING THE ABILITY TO METABOLIZE PHARMACEUTICALS AND COMPOSITIONS THEREFOR," for which application for Letters Patent of the United States has been made by Marco Guida, Jeff Hall, William P. Petros, James J. Vredenburg, Oliver M. Colvin, and Jeffrey R. Marks, said application having been filed on February 26, 2002, receiving Serial No. 10/085,612, and further identified as Attorney File No. 4389-5-C1, I hereby appoint David F. Zinger, Registration No. 29,127; Craig C. Groseth, Registration No. 31,713; Sabrina C. Stavish, Registration No. 33,374; Todd P. Blakely, Registration No. 31,328; Lewis D. Hansen, Registration No. 35,536; Joseph E. Kovarik, Registration No. 33,005; Gary J. Connell, Registration No. 32,020; Douglas W. Swartz, Registration No. 37,739; Bruce A. Kugler, Registration No. 38,942; Robert R. Brunelli, Registration No. 39,617; Brent P. Johnson, Registration No. 38,031; Dana Hartje Cardwell, Registration No. 40,638; Angela K. Dallas, Registration No. 42,460; Benjamin B. Lieb, Registration No. 42,801; Bradley M. Knepper, Registration No. 44,189; Miriam Drickman Trudell, Registration No. 42,499; Dennis J. Dupray, Registration No. 46,299; Kenneth C. Winterton, Registration No. 48,040; Robert D. Traver, Registration No. 47,999; Mark L. Yaskanin, Registration No. 45,246; and Mollybeth R. Kocialski, Registration No. 42,754, of SHERIDAN ROSS P.C., 1560 Broadway, Suite 1200, Denver, Colorado 80202-5141, telephone number (303) 863-9700, as attorneys and agents for Duke University, with full powers of substitution, association and revocation to prosecute the application and related U.S. and foreign applications and to transact all business in the United States Patent and Trademark Office and all foreign and international patent offices connected therewith.

By: 

Name: Robert L. Taber

Title: Vice Chancellor of Science & Technology  
Development

Date: May 8, 2002

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OFFICE OF PETITIONS



## POWER OF ATTORNEY

On behalf of DNA Sciences, Inc., a Delaware corporation having a principal place of business at 6540 Kaiser Drive, Fremont, California 94555 being the assignee and owner of all right, title and interest in the invention entitled "METHODS FOR EVALUATING THE ABILITY TO METABOLIZE PHARMACEUTICALS AND COMPOSITIONS THEREFOR," for which application for Letters Patent of the United States has been made by Marco Guida, Jeff Hall, William P. Petros, James J. Vredenburg, Oliver M. Colvin, and Jeffrey R. Marks, said application having been filed on February 26, 2002, receiving Serial No. 10/085,612, and further identified as Attorney File No. 4389-5-C1, I hereby appoint David F. Zinger, Registration No. 29,127; Craig C. Groseth, Registration No. 31,713; Sabrina C. Stavish, Registration No. 33,374; Todd P. Blakely, Registration No. 31,328; Lewis D. Hansen, Registration No. 35,536; Joseph E. Kovarik, Registration No. 33,005; Gary J. Connell, Registration No. 32,020; Douglas W. Swartz, Registration No. 37,739; Bruce A. Kugler, Registration No. 38,942; Robert R. Brunelli, Registration No. 39,617; Brent P. Johnson, Registration No. 38,031; Dana Hartje Cardwell, Registration No. 40,638; Angela K. Dallas, Registration No. 42,460; Benjamin B. Lieb, Registration No. 42,801; Bradley M. Knepper, Registration No. 44,189; Miriam Drickman Trudell, Registration No. 42,499; Dennis J. Dupray, Registration No. 46,299; Kenneth C. Winterton, Registration No. 48,040; Robert D. Traver, Registration No. 47,999; Mark L. Yaskanin, Registration No. 45,246; and Mollybeth R. Kocialski, Registration No. 42,754, of SHERIDAN ROSS P.C., 1560 Broadway, Suite 1200, Denver, Colorado 80202-5141, telephone number (303) 863-9700, as attorneys and agents for DNA Sciences, Inc., with full powers of substitution, association and revocation to prosecute the application and related U.S. and foreign applications and to transact all business in the United States Patent and Trademark Office and all foreign and international patent offices connected therewith.

By: 

Name: Steven B. Lehrer

Title: President and COO

Date: 5/30/02

**POWER OF ATTORNEY CONCERNING A GIVEN  
INTERNATIONAL APPLICATION**

Patent Cooperation Treaty  
Appointment of Agent or Common Representative

The undersigned applicant hereby appoints

Gary J. Connell  
Registration No. 32,020  
and

David F. Zinger	Reg. No. 29,127
Craig C. Groseth	Reg. No. 31,713
Todd P. Blakely	Reg. No. 31,328
Gary J. Connell	Reg. No. 32,020
Sabrina Crowley Stavish	Reg. No. 33,374
Joseph E. Kovarik	Reg. No. 33,005
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Brent P. Johnson	Reg. No. 38,031
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Angela Dallas-Pedretti	Reg. No. 42,460
Benjamin B. Lieb	Reg. No. 42,801
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Kenneth C. Winterton	Reg. No. 48,040
Robert D. Traver	Reg. No. 47,999
Mark L. Yaskanin	Reg. No. 45,246
Mollybeth R. Kocalski	Reg. No. 42,754

of Sheridan Ross P.C., 1560 Broadway, Suite 1200, Denver, Colorado 80202-5141 as agents to represent the undersigned before all the competent International Authorities in connection with the international application entitled "METHODS FOR EVALUATING THE ABILITY TO METABOLIZE PHARMACEUTICALS AND COMPOSITIONS THEREFOR", Attorney Docket No. 4389-5-C1-PCT, filed with U.S. Receiving Office and to make or receive payments on their behalf.

APPLICANT: GUIDA, Marco  
3899 Nobel Drive, #1301  
San Diego, California 92122  
United States of America / Italy

Date: \_\_\_\_\_

By: \_\_\_\_\_  
Marco Guida

## ASSIGNMENT

WHEREAS, we, Marco Guida of 3899 Nobel Drive, #1301, San Diego, California 92122 and Jeff Hall of 7226 Columbine Drive, Carlsbad, California 92009, along with co-inventors William P. Petros of 2 Bermouth Court, Durham, North Carolina 27705; James J. Vredenburg of 100 Silver Glade Place, Chapel Hill, North Carolina 27514; Oliver M. Colvin of 208 Arcadia Lane, Chapel Hill, North Carolina 27514; and Jeffrey R. Marks of 4233 New Hope Spring Drive, Hillsborough, North Carolina 27278, have invented a certain new and useful invention entitled "METHODS FOR EVALUATING THE ABILITY TO METABOLIZE PHARMACEUTICALS AND COMPOSITIONS THEREFOR," for which an application for Letters Patent of the United States was filed on February 26, 2002, receiving Serial No. 10/085,612, and further identified as Attorney File No. 4389-5-C1 and for which a PCT application was filed on February 26, 2002, receiving Serial No. PCT/US02/06135 and further identified as Attorney File No. 4389-5-C1-PCT.

NOW THEREFORE, be it known that we, the said inventors, for and in consideration of certain good and valuable consideration, the sufficiency and receipt of which is hereby acknowledged, at the request of the assignee do sell, assign and transfer unto said assignee, DNA Sciences, Inc., a Delaware corporation having a place of business at 6540 Kaiser Drive, Fremont, California 94555, its successors, legal representatives and assigns, the aforesaid application for the territory of the United States of America and all continuation, divisional, continuation-in-part and reissue applications, all patent applications in foreign countries, all applications pursuant to the Patent Cooperation Treaty, and all applications for extension filed or to be filed for the invention, and all Letters Patent, Invention Registrations, Utility Models, Extensions or Reissues and other patent rights, obtained for the invention in the United States or any other country; we also assign any right, title or interest in and to the invention which has not already been transferred to the assignee; we warrant that we have made no assignment of the invention, application or patent therefor to a party other than DNA Sciences, Inc. and we are under no obligation to make any assignment of the invention, application, or patent therefor to any other party; and we further agree to cooperate with the assignee hereunder in the obtaining and sustaining of any and all such Letters Patent and in confirming assignee's exclusive ownership of the invention, but at the expense of said assignee.

The Commissioner of Patents is hereby authorized and requested to issue the Letters Patent in accordance with the terms of this Assignment, to DNA Sciences, Inc., its successors, legal representatives and assigns, as the assignee of the entire right, title and interest of inventors Marco Guida and Jeff Hall therein.

IN WITNESS WHEREOF, the parties hereto have executed this Assignment as of the date indicated hereunder.

Date: \_\_\_\_\_

By: \_\_\_\_\_  
Marco Guida

Date: \_\_\_\_\_

By: \_\_\_\_\_  
Jeff Hall

STATE OF

)

) ss.

COUNTY OF

)

Before me, a Notary Public in and for said County and State, personally appeared Marco Guida, known to me to be the person whose name is subscribed to the foregoing instrument, and acknowledged to me that he executed the same for the purposes and considerations therein expressed.

Given under my hand and seal of office this \_\_\_\_\_ day of \_\_\_\_\_, 2002.

\_\_\_\_\_  
Notary Public

My Commission Expires: \_\_\_\_\_

STATE OF

)

) ss.

COUNTY OF

)

Before me, a Notary Public in and for said County and State, personally appeared Jeff Hall, known to me to be the person whose name is subscribed to the foregoing instrument, and acknowledged to me that he executed the same for the purposes and considerations therein expressed.

Given under my hand and seal of office this \_\_\_\_\_ day of \_\_\_\_\_, 2002.

\_\_\_\_\_  
Notary Public

My Commission Expires: \_\_\_\_\_

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(1) Inventor's Signature \_\_\_\_\_ Date \_\_\_\_\_

Inventor's Name (typed): Marco Guida

Citizenship: Italy

Residence: 3899 Nobel Drive, #1301  
San Diego, California 92122

Post Office Address\*: Same as Residence

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(2) Inventor's Signature \_\_\_\_\_ Date \_\_\_\_\_

Inventor's Name (typed): Jeff Hall

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37 CFR §1.56(a) and (b)  
DUTY TO DISCLOSE INFORMATION MATERIAL  
TO PATENTABILITY

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

(1) prior art cited in search reports of a foreign patent office in a counterpart application,  
and

(2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

- (i) Opposing an argument of unpatentability relied on by the Office, or
- (ii) Asserting an argument of a patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.\*

\*Note, 37 CFR §1.97(h) states: "The filing of an information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in §1.56(b)."